Safety instructions

Read this manual carefully, because it contains important information on using and servicing the tonometer.

- Keep this manual for future use.
- When you have opened the package, check for any external damage or faults. Check especially that the casing is not damaged. If you suspect that there is something wrong with the tonometer, contact the manufacturer or the distributor.
- Use the tonometer only for measuring intraocular pressure. Any other use is incorrect. The manufacturer cannot be held responsible for any damage arising from improper use, or for the consequences thereof.
- Never open the casing of the tonometer, except for the battery compartment or to change the probe base.
- The manual contains instructions for replacing batteries and changing the probe base.
- Never use the tonometer in wet place.
- The probe base, battery compartment cover, collar and probes are so small that a child could swallow them. Keep the tonometer out of the reach of children.
- Do not use the device near the substances that are flammable - including flammable anaesthetic agents.
- Check that a clean new disposable probe is used before each measurement.
- Be sure that the probe contains the small plastic round tip in front.
- Certain microbiological agents (e.g. bacteria) can be transmitted from the forehead support. To avoid this, the forehead support should be cleaned regularly with a disinfectant, e.g. an alcohol solution.
- The tonometer must not come into contact with the eye, except for the probes for a fraction of a second during the measurement, therefore Do not bring the tonometer into contact with the eye or push it to the eye (tip of the probe should be 4-8mm from eye).
- The tonometer conforms to EMC requirements (IEC 60101-1-2: 2001), but interference may occur in it if used near to (<1m) a device causing high-intensity electromagnetic emissions (like a cellular phone). Though the tonometer's own electromagnetic emissions are well below the levels in the relevant standards, they may cause interference in another device, e.g. a sensitive sensor, nearby.
- If the device is not to be used for a long time, removing the batteries is recommended, as the AA batteries may leak. Removing the batteries will not affect the subsequent functioning of the tonometer.
- Be sure to dispose of the one-use probes properly (e.g., in a container for disposable needles), because they may contain micro-organisms from the measured patient.
- Batteries, packaging materials, and probe bases must be disposed of according to local regulations.

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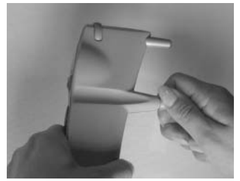
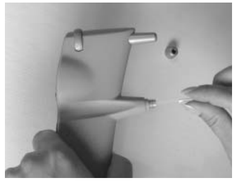
Replacing the probe base

After several months of use, dust may collect in the probe base, affecting the probe movement. The probe base should be replaced if the probe no longer moves smoothly.



Unscrew the probe base collar and put it in a safe place.

Remove the probe base by tilting the tonometer downward and pull the probe base out of the tonometer.



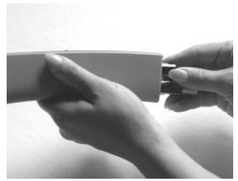
Put a new probe base into the tonometer.

Screw the collar in, to lock the probe base.

Replacing the batteries

Unscrew the battery compartment locking screw with a screwdriver or a small coin.

Remove the battery compartment cover.



Remove the old batteries.

Put new AA batteries into the tonometer according to figures inside the battery compartment.
+ terminals should be down on the display side of the tonometer (behind).
- terminals should be up on the measurement side (the front side).

Replace the battery compartment cover and secure it in place by screwing it lightly with the coin or screwdriver. Be careful not to use excessive force when screwing the cover in place.

Error messages:

Press the central button to clear error messages, after which the measurement can be repeated.

The following messages may appear:

- bAtt ..... the batteries are low. Replace the batteries.
- E01 ..... The probe did not move at all.
  If this error message is repeated, turn the tonometer so that the collar faces down for a short time. If the error message is still repeated take out the probe and replace with a new one. If the error message continues to appear, replace the probe base.
- E02 .....The probe did not touch the eye.
  The measurement was made from too far away or the probe base is dirty.
- E03 .....Probe speed was too low.
  The measurement was made from too far away or the tonometer was tilted upwards too much.
- E04 .....Probe speed was too high.
  The tonometer was tilted downwards. Be sure the groove is in the horizontal position.
- E05 .....The hit was too "soft".
  The probe hit the eyelid.
- E06 .....The hit was too "hard".
  The probe hit the opening eyelid or calcification in the cornea.
- E07 .....Bad bounce".
  The probe did not hit the central cornea.

Service procedures

- Replace the batteries when the <bAtt> message appears.
- Change the probe base if the probe does not move smoothly.
- There are no other service procedures that can be carried out by the user. All other servicing and repairs must be carried out by the manufacturer or certified service facilities.
- The device can be cleaned with a damp cloth containing desinfectant.

Technical information

Type: TA01.
The device conforms to CE-regulations.
Dimensions: 13 – 32 mm (W) * 45 – 80 mm (H) * 230 mm (L).
Weight: 155 g (without batteries) , 250 g (4 x AA batteries).
Power supply: 4 x AA batteries.
Measurement range: 1-99 mmHg.
Accuracy of display: ±1.
Measurement accuracy: ±2,8 mmHg (5-30 mmHg), 15% (30-80 mmHg).
Display unit: Millimetre mercury (mmHg).
The serial number is on the back of the battery compartment cover.
There are no electrical connections from the tonometer to the patient.
The device has B-type electrical shock protection.
Storing/transportation environment:
Temperature +5 to +40 °C
Rel. humidity 10 to 80 % (without condensation)

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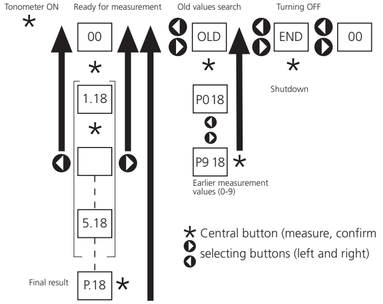
CAUTION -Indicates that important operating instructions are included in this User's and Maintenance Manual.

Spare parts and supplies

- Probes in one-use package.
- Probe base replacement kit.

Diagram of tonometer functions



icare® Tonometer

USER'S AND MAINTENANCE MANUAL

FOR FUTURE VISION

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Introduction

The iCare-Tonometer is used in the diagnosis, follow up, and screening of glaucoma.

The iCare is based on the new patented induction based rebound method, which allows intraocular pressure (IOP) to be measured accurately, rapidly and without an anaesthetic.

There is no risk of microbiological contamination, as one-use probes are used in the measurement.

Intraocular pressure changes due to the effects of pulse, breathing, eye movements, and body position. Because the measurement is made handheld in fractions of a second, several measurements are needed to obtain an accurate reading. The software is pre-programmed for six measurements, but the result can be seen from the first successful measurement.

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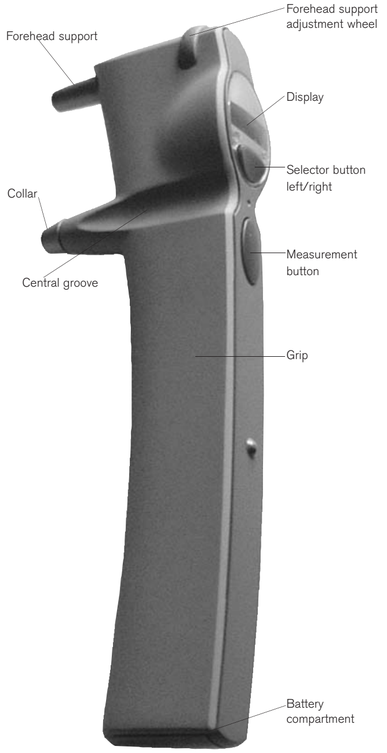
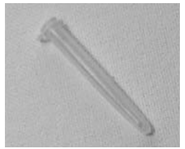
Parts of the tonometer





Accurate measurement is guaranteed only when using probes made by Tiolat Oy.

Hold the disposable probe in your hand, open the package, and load the probe into the sensor base, according to the illustrations.

Place the opened disposable package against the collar component.

Turn to the device and the probe package at the same time, so that the probe package is uppermost. Check that the probe has dropped into the probe base before removing the package.

The probe in the probe base.

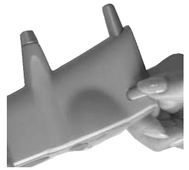
Loading a new disposable probe

Turning the device ON and magnetizing the probe

Raise the device to the vertical operating position, ensuring that the probe cannot fall out of the probe base. Press the measurement button. The probe will be magnetized by moving back and forward for a short time, and the mechanism that prevents the probe dropping out accidentally will start.

The device is ready for measurement when the reading 00 appears in the display.
If the display shows the message LoAd, there is either no probe in the device, or the probe is stuck. Check that the probe has not dropped out, or press the function button again.

Adjusting the forehead support



The forehead support can be adjusted back and forward by turning the adjustment wheel. This allows the correct measurement distance to be set for each individual.

Measurement

The measurement should be done without anesthetic, because an anesthetic may reduce the tonometer reading*.

Ask the subject to relax and look straight ahead to a specific point. Bring the tonometer near to the subject's eye. The central groove should be in a horizontal position. The distance from the eye to the front part of the collar is the length of the collar. The distance should be 4-8 mm from the tip of the probe to the cornea of the eye. If necessary, adjust the distance by turning the forehead-support adjustment wheel.

Measure takes place by lightly pressing the measurement button. The tip of the probe should hit the central cornea. Six measurements are made consecutively. Press the measurement button carefully, to avoid shaking the tonometer. After each successful measurement there is a short beep. After the six measurements, the IOP is shown on the display after the P letter.

If there is an erroneous measurement, the tonometer will beep twice and show an error message (page 10). Press the measurement button to clear the error message. If several erroneous measurements appear, see the section "Error messages" (page 10).

Display after the measurements:

Before	After the second measurement	After the sixth measurement.
00	**2.13**	**P 13**

After the sixth measurement, the letter P appears in the display, followed by the IOP (Intraocular pressure) reading.

If the P is blinking, it means that the standard deviation of the measurements is greater than normal.

P_ (line down) The standard deviation of different measurements is slightly bigger value than normally, but the effect to the result is not likely to be relevant.

P– (line in the middle) The standard deviation of different measurements is clearly greater than normal, but the effect on the result is usually not relevant. A new measurement is recommended if the IOP is more than 19 mmHg.

P¯ (line up) The standard deviation of different measurements is great and a new measurement is recommended.

•Badouin C, Gastaud P. Influence of topical anesthesia on tonometeric values of intraocular pressure. Ophthalmologica 1994;208:309-313

Other functions

Accessing old measurement values.

Starting position.

Press the right or left selector button until Old appears on the display. Then press the measurement button. The old values can now be scanned back and forward by pressing the selector buttons (right= older, left=recent).

Press the measurement button to exit the old values search. Old is on the display. Press either of the selector buttons to access the other functions (00=measurement, End=turning OFF).

Turning the tonometer OFF

Press either of the selector buttons until the display shows End.

Press the measurement button for two seconds – The display shows ByE and the tonometer turns off.
The used probe is ejected from the tonometer Be careful to dispose of the probe properly (p.7).

The tonometer turns off automatically after two minutes idle time.